

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 14, 2019

<p>* * * * *</p> <p>KIM MAILANGKAY,</p> <p style="text-align: center;">Petitioner,</p> <p>v.</p> <p>SECRETARY OF HEALTH AND HUMAN SERVICES,</p> <p style="text-align: center;">Respondent.</p> <p>* * * * *</p>	<p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p>	<p>UNPUBLISHED</p> <p>No. 18-36V</p> <p>Special Master Gowen</p> <p>Motion for Dismissal Decision; Influenza (“Flu”); Bell’s palsy; Migraine Disorder.</p>
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Jay M. Mall, Department of Justice, Washington, D.C.

DECISION DISMISSING PETITION¹

On January 5, 2018, Kim Mailangkay (“petitioner”) filed a petition in the National Vaccine Injury Compensation Program (“Vaccine Program”).² Petitioner alleges that she developed Bell’s palsy, migraines with aura, disequilibrium and depression as a result of receiving an influenza vaccine on October 5, 2015. Petition at Preamble (ECF No. 1). Petitioner filed medical records and an expert report from Dr. Lawrence Steinman. Notice of Filings (ECF Nos. 6-9). Respondent filed a Rule 4(c) report on March 13, 2019, recommending that entitlement to compensation be denied. Respondent’s (“Resp.”) Report (ECF No. 26). The same day, respondent filed an expert report from Drs. Robert Fujinami and Dara Jamieson. Resp. Exhibit (“Ex.”) A & C (ECF No. 27). The undersigned held a Rule 5 Status Conference on May 9, 2019.

During the Rule 5 status conference, I reviewed the medical records, expert reports and the medical literature filed by both parties. I observed that the medical records filed in this case show

¹ Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), **because this decision contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The court’s website is at <http://www.uscfc.uscourts.gov/aggregator/sources/7>. Before the decision is posted on the court’s website, each party has 14 days to file a motion requesting redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). “An objecting party must provide the court with a proposed redacted version of the decision.” *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court’s website without any changes.** *Id.*

² The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended at 42 U.S.C. §§300aa-10 *et seq.* (hereinafter “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. §300aa of the Act.

that petitioner's Bell's palsy symptoms improved throughout the winter of 2015 into 2016 and had mostly resolved by March 22, 2016. *See* Pet. Ex. 3 at 110; 124; 140, 208 & 229; Pet. Ex. 5 at 3-5. The undersigned stated that it appears that petitioner's Bell's palsy resolved before meeting the six-month severity requirement in the Vaccine Program.³ Petitioner's counsel stated that petitioner's migraines, however, continued past six months.

Additionally, petitioner's migraine disorder first appeared as her Bell's palsy symptoms were dissipating. She first reported headaches in December 15, 2015. Pet. Ex. 3 at 118. Petitioner described them as "left sided" and "worse at the end of the day." *Id.* She was diagnosed by tension headaches and advised to take NSAIDS. In March 22, 2016, petitioner was diagnosed with "classic migraine" by Dr. Nielsen. *Id.* at 226. At the same time, petitioner reported her Bell's palsy symptom as having resolved. Pet. Ex. 5 at 5.

Petitioner's expert, Dr. Steinman, opined that petitioner's development of the initial Bell's palsy was caused by the Fluzone vaccine she received on October 5, 2015 and invoked the theory of molecular mimicry to satisfy *Althen Prong 1*. Petitioner's Exhibit ("Pet. Ex.") 9 at 24. Dr. Steinman also observed that the Fluzone package insert, approved by the FDA, provides that "facial palsy (Bell's palsy)" and "paresthesia" have been reported during the post-approval use of the trivalent formulation of Fluzone. *Id.* at 8-9. He then turned to petitioner's migraine disorder and opined that the petitioner's "Bell's palsy also triggered the subsequent migraine disorder." Pet. Ex. 9 at 24. However, as discussed in detail in the Rule 5 Order, the study Dr. Steinman referenced in support of the association between Bell's palsy and migraines concluded that migraine is a risk factor for Bell's palsy, but not that Bell's palsy is a precursor to migraines, as was the case for petitioner. *See* Rule 5 Scheduling Order (ECF No. 28).

The undersigned agreed with respondent's expert, Dr. Jamieson, who stated that the study referenced by Dr. Steinman, deduced that during a period of several years, more people with migraine developed Bell's palsy than did people without migraine. Resp. Ex. C at 10. Further, Dr. Jamieson correctly observes that migraine is a common, chronic disease while Bell's palsy is much rarer, acute and self-limited event. *Id.*

The undersigned stated that based on the clinical history of petitioner's neurological condition and the medical literature not supporting Dr. Steinman's assertion that petitioner's Bell's palsy triggered her subsequent migraine disorder, it would be unlikely that she would be successful in this claim. Petitioner's counsel requested the opportunity to consult with his expert and his client.

On May 10, 2019 petitioner filed the present motion to dismiss her claim, stating that after conferring with her medical expert, she has decided to voluntarily dismiss her claim pursuant to Vaccine Rule 21(a). Pet. Mot. For Voluntary Dismissal (ECF No. 29).

A petitioner must establish entitlement to compensation in the Vaccine Program through

³ Under the National Vaccine Injury Compensation Program, a petition for compensation must show that the petitioner has suffered the residual effects or complications of such illness, disability, injury or condition for more than six months after the administration of the vaccine. 42 U.S.C. §300aa-11(c)(D)(i).

one of two ways. The first way is to establish that he or she suffered a “Table injury,” i.e., that he or she received a vaccine listed on the Vaccine Injury Table and subsequently developed a corresponding injury within a corresponding period of time. § 300aa-11(c)(1). The second way is to establish that the vaccine actually caused the onset or significant aggravation of a condition in the vaccinee. § 300aa-13(a)(1)(A). To prove actual causation, petitioner must present: (1) a medical theory; (2) a logical sequence of cause and effect; and (3) a medically acceptable temporal relationship between the vaccination and the injury. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

In the present cast, petitioner does not allege a Table injury. Thus, to prevail on entitlement, petitioner must establish that the flu vaccine she received is the actual cause of her injuries. Under the Vaccine Act, a petitioner may not be awarded compensation based solely on the petitioner's claims. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

The petitioner’s clinical history of her neurological condition does not support causation. As discussed above, petitioner’s Bell’s palsy resolved before she developed a migraine disorder. The medical literature submitted by Dr. Steinman supported a relationship between individuals with migraine being at risk of developing Bell’s palsy, but not that Bell’s palsy is a precursor to developing migraines. *See* Pet. Ex. 30.

In this case, there is insufficient evidence in the record for petitioner to meet her burden under the Act or *Althen*. Petitioner’s claim therefore cannot succeed and in accordance with her motion, must be dismissed for insufficient proof.

Thus, this case is dismissed for insufficient proof. The Clerk of the Court shall enter judgment accordingly.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master